Claims 2, 7-9, 12-32, 44, 49-51, 56-57, 63, 65-81, 88-97, 101, 103-108, 120-122, 124, and 130-131 are currently pending in the application.

The Examiner is respectfully requested to reconsider and withdraw the various rejections in light of the comments that follow.

The invention

Applicants' invention solves a particular problem as highlighted in Applicants' previous responses. The problem encountered by the applicants was how to effect controlled release of a low-solubility drug from an osmotic dosage form comprising a bilayer, coated tablet. To deliver the low-solubility drug, a drug entraining agent was necessary since the drug is generally extruded as a viscous suspension due to its low solubility. However, the low-solubility drug and the additional mass of the entraining agent necessitated a highly swelling material such as sodium glycolate or cross carmellose sodium to push the drug composition out of the dosage form. The highly swelling materials, in turn, presented a separate problem in that the highly swelling materials were difficult to compress into tablets of sufficient strength that don't chip or break apart extensively during the manufacturing process. See, for example, page 30, lines 31-33 of the application where the problem is highlighted:

> The preferred swelling agents (e.g., those that are highly swelling) are difficult to compress to a hardness suitable for use in the dosage form.

The aforementioned problem is by no means trivial from a manufacturing perspective in that, although a highly swelling material for use in the push layer is desirable for its ability to completely or nearly completely extrude the drug composition, such highly swellable materials are generally friable and, as a consequence, contribute to the chipping and breakage.

Thus, the inventors solved the problem of delivering a low-solubility drug while maintaining sufficient tablet strength by (1) using an entraining agent (2) selecting highly swelling materials for the push layer and (3) adding a tableting aid to ease compression. The swelling materials and tableting aids are specifically recited in the claims.

The Rejections And Applicants' Traversal

Claims 64-66 were objected to as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 64 has now been canceled, thus obviating the rejection as to that claim. The Examiner is requested to reconsider the rejection insofar as claims 65 and 66 are concerned. Each of claims 65 and 66 defines a subset within the category of drugs that have "low-solubility", namely drugs that are "substantially water insoluble" and drugs that are "sparingly water soluble". Both subsets are defined as having different degrees of solubility within the category of drugs that Applicants termed "low solubility". See Applicants' specification at page 12, lines 18-27, which defines all three terms. Thus claims 65 and 66 do further limit the subject matter of claim 2 beyond "low-solubility". Each of claims 65 and 66 defines a different subset of solubilities that are subsets within the more generic "low solubility" category, and thus both of claims 65 and 66 further limit claim 2. Applicants accordingly request that, as to claims 65 and 66, the rejection be withdrawn.

Claims 118-119 were rejected under 35 USC §112, second paragraph as being indefinite in that they contradicted the claim limitations in claim 2, their parent claim. The claims have now been canceled, thus obviating the rejection.

All of the claims, with the exception of claim 57, continue to be rejected under 35 USC §103(a) over Wong in view of Stevens, optionally further in view of Park. The reasoning underlying the rejection parallels that from past Office Actions.

Applicants traverse the rejection as being based on hindsight. It is Applicants' position that nothing in any of the references, or in their combination, discloses or suggests the problem or solution found by the applicants. Applicants' remarks from their previous response (responding to the Office Action mailed on 7/26/04) are incorporated herein by reference.

At page 4, the examiner states Wong discloses the mass ratio of the first composition to the second composition at column 16. It is respectfully submitted that the examiner is incorrect. Column 16 discloses generally mass ratios of the first osmopolymer in Wong to the second polymer, but does not say anything about the need for the mass of the drug composition to be greater than the mass of the swelling composition, as required by Applicants. This is important, since to maximize drug loading in the tablet, one wants the sweller layer to have less mass than the drug layer.

Stevens simply discloses a slug of a disintegrant and a tableting aid, but makes no suggestion or motivation to use them in an osmotic bilayer tablet.

The examiner continued to take the position that tablets and capsules are the same. See page 9, last paragraph where the Examiner stated:

> With regard to the combination of a tablet reference and capsule reference, the examiner suggests that the applicant provide evidence that the methods of making capsules and tablets are vastly different and thus one would not be able to combine the two references. Until such evidence is provided, the examiner maintains her position since Wong's expandable excipient and Stevens' expandable excipient function in a similar manner, i.e., to swell and push the active out of the dosage form. Moreover, Wong also states that although capsules and tablets have different shapes, they act in a similar manner to let fluid into the core. See column 8-9.

Applicants respectfully disagree that teachings applicable to the Stevens capsule are automatically applicable to tablets, for the reasons that follow.

First, it is well known in the art that tablets are formed by compressing the materials to a required hardness, and then coating them. It is necessary that the tablets are compressed to a relatively high strength so that the tablets remain intact during the coating process. In distinct contrast, capsules are formed using filling machines. There is no need for the contents to be of a particular strength, since the capsule wall, or coating, is preformed. There is thus no reason to consider the problem of capsule breakage or chipping as there is for tablets.

Second, Stevens provides no motivation for combining any particular hydrogel he discloses, including from his Example 10, with Wong. In the absence of some reason or motivation for doing so, it would be untenable and totally arbitrary for one of ordinary skill in the art to zero in on the swelling agent disclosed in Stevens' Example 10 over any other swelling agent (or combination of swelling agents) that Stevens also discloses, but that would be outside the requirements of Applicants' claim 2, and that would not provide the advantages that Applicants specifically sought in respect of manufacturing tablets.

The Examiner took the position that it would be obvious to combine the teachings of Stevens and Wong simply because the Stevens swelling agents are highly swelling (first full paragraph, page 7). The Examiner reinforced that position by stating (as quoted above), that "...the Examiner maintains her position since Wong's expandable excipient and Stevens expandable excipient function in a similar manner, i.e. to swell and push the active out of the dosage form." See page 9 of the Office Action, bottom four lines. Applicants respectfully disagree. All of the many swelling agents recited in Stevens presumably function to swell and push active out of the dosage form. But, that

begs the question of why, in the absence of a motivation for doing so, would one of ordinary skill choose the swelling agent of example 10 over any of the other swelling agents also disclosed in Stevens that are outside the scope of Applicants' claims, **for use as the swellable layer in a tablet.** Even though all of the swelling agents and/or swelling agent combinations disclosed in Stevens presumably function to push out active, the great majority of those swelling agents are outside Applicants claims. As Stevens is directed to capsules, Stevens provides no motivation for choosing any one swelling agent over any other for use **in a tablet**. It is by mere chance alone that one of ordinary skill would choose a combination such as the combination disclosed in Stevens Example 10.

Further, even allowing *arguendo* that one of ordinary skill reading Stevens might try the highly swelling materials (disintegrants) of Stevens in a tablet, one would not find it obvious to combine the sweller with Applicants' tableting aid. As shown in Table 12 of the application, the presence of a tableting aid generally decreases the swelling ratio of the swelling agent, yet Applicants' claims require that the tableting aid be present in an amount of at least 20wt%. Applicants' use of a tableting aid represents a balancing of the need for a highly swelling material with the need to form a compressed tablet of high strength. Because Stevens is concerned with a capsule, rather than a compressed tablet, these issues do not arise since Stevens is dealing with a preformed capsule shell. Stevens does not address this issue and does not point a person skilled in the art to the particular combination of a highly swelling agent and tableting aid in a tablet.

The arguments presented above form the basis for Applicants' position that the rejection is based on hindsight. The only reason one of ordinary skill would find the swelling agent/tableting aid combination required by Applicants to be obvious (e.g., the combination of Stevens' Example 10) for use **in a tablet** is if he or she had the benefit of Applicants' own disclosure. But, Applicants' disclosure cannot be used against them to support the rejection, in essence using the specification as a template to take various components from the prior art and re-assemble them into Applicants' invention. There is simply no suggestion otherwise as between Wong and Stevens to combine the swelling agent of Stevens Example 10, rather than any of the numerous other Stevens swelling agents that are outside Applicants claims', with the tablet of Wong. There is no suggestion in Stevens that any benefit would accrue. Indeed, that is the essence of a rejection based on the forbidden use of hindsight, as Applicants' respectfully submit has happened here.

The Examiner also rejected all of the claims over Wong and Stevens, optionally further in view of Park. The examiner argued that Park discloses that disintegrants provide mechanical strength to hydrogels and, therefore, that this disclosure supplies the motivation to include Park in with the Stevens/Wong combination. Applicants traverse on the basis that Park is not relevant, and that the combination is untenable for that reason. Park is concerned with a hydrogel used as a gastric retention device. The mechanical strength referred to in Park is the strength of the swollen hydrogel, so that the hydrogel will remain intact within the stomach to function as a gastric retention device. In contrast, as discussed above, the swelling agents of the present invention actually make tablets, as opposed to Park's hydrogel, more difficult to compress to the desired strength. It is accordingly respectfully submitted that Park does not support the Examiner's argument that a person skilled in the art would use sodium starch glycolate or cross carmellose sodium to increase "mechanical strength", since the (1) the mechanical strength referred to in Park relates to that of the swollen hydrogel, which is not of concern for osmotic bilayer tablets and (2) the presence of these materials generally makes it more difficult to make a compressed tablet of the desired strength. Because of the increased difficulty in making a compressed tablet, Applicants use a tabletting aid to increase tablet strength.

Claim 57 continues to be rejected over Wong et al. in view of Stevens et al, optionally in further view of Park, and in further view of the Jim Kling article. Applicants traverse the rejection on the basis that it fails to remedy the deficiencies of the Wong/Stevens/optional Park combination, as discussed above. Kling was cited simply for its teaching of Viagra® as a drug for hypertension or erectile function. Wong, Stevens and Park appear to have been cited for the reasons set forth by the Examiner in rejecting the remaining claims. Applicants note that claim 57 depends directly from claim 2. The rejection is traversed on the basis that the combination of Wong and Stevens is fatally defective for the reasons advanced above in Applicants discussion of claim 2 in relation to Wong and Stevens, and Applicants' comments relating to Wong and Stevens are incorporated herein by reference in this respect. It is respectfully submitted that the Kling article, beyond its disclosure of sildenafil citrate, does nothing otherwise to remedy the fatal defects of Wong and Stevens, whether or not those references are combined with Park.

Double Patenting

Claims 2, 7-9, 12, 15-32, 44, 49-51, 56, 57, 63-81, 88-97, 101, 103-108, 118-122, 124, 130, 131 were rejected for obviousness-type double patenting over claims 1-3 and 5-20 of co-pending Application No. 10/344,171 and over the claims of Application No. 09/745,096. It is noted that the '096 application has now issued as US 6,899,896.

As background, it is noted that double patenting analysis is based on a comparison of the claims at issue to the claims in the reference patent, not its disclosure. Thus, the Federal Circuit reversed a finding of double patenting notwithstanding the full disclosure of the invention of the second patent by the claim of the first patent, explaining that:

> [I]t is important to hear in mind that comparison can be made only with what invention is *claimed* in the earlier patent, paying careful attention to the rules of claim interpretation to determine what invention a claim *defines* and not looking to the claim for anything that happens to be mentioned in it as though it were a prior art reference.

(*General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1280, 23 U.S.P.Q.2d 1839, 1845 (Fed. Cir. 1992); *see also In re Sarett*, 327 F.2d 1005, 1013, 140 U.S.P.Q. 474, 481 (C.C.P.A. 1964)

The rejection is traversed. First, no composition within the scope of Applicants' claims is disclosed in the claims of either of the double patenting references. Although some of the ingredients useful in the invention of the instant claims and of the inventions defined in the claims of the double patenting references overlap, no claim or combination of claims in either double patenting reference provides any basis for rendering obvious a tablet having a core strength of at least 3 Kp/cm^2 in which the mass ratio of the drug-containing composition to the water-swellable composition has a value of at least 3.5 and in which the tablet has a tableting aid that comprises at least 20 wgt % of the water-swellable composition. The Office has provided no basis for concluding that one of ordinary skill would conclude that a tablet having this level of strength, under conditions in which the mass ratio and amount of tabletting aid just quoted have the required values, is obvious. The claims in the double patenting references otherwise shed no light on the problem solved by Applicants, the solution to that problem, or the benefits that accrue. Applicants' accordingly respectfully submit that the claims of the double patenting references provide no basis for concluding that a tablet having the combination

of properties required by the claims of the instant invention are obvious. Withdrawal of the rejection is accordingly respectfully requested.

In view of the foregoing comments and amendments, It is accordingly respectfully requested that all rejections be withdrawn. In view of the comments and amendments, this application is believed to be in condition for allowance, and a Notice of Allowance is courteously solicited.

Respectfully submitted,

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